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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,271

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Michael P. Whitman

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,271	Applicant(s) WHITMAN ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,15-20,28-33 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,15-20,28-33 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 20 there is an inconsistency with the language of the preamble in claim 1 and that of the body of the claim thus making their scope unclear. The preamble in claim 1 recites "an orifice introducer device" indicating that the claims are directed to the subcombination introducer. However, claim 20, positively recites the "surgical device", as an element of invention, thus indicating that the claims are directed to the combination of the introducer and the surgical device. As such it is unclear whether applicant intends the claims to be drawn to the combination or the subcombination. Applicant is hereby required to indicate which, the combination (a system including an introducer and surgical device) or subcombination (the introducer), the claims are intended to be drawn and make the language consistent with this intent. For examination purposes, the claims will be considered as drawn to the combination (introducer with surgical device).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11, 12, 15-17, 28, 31-33 and 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Dormia et al (USPN 5,176,127).

5. Dormia discloses an introducer (Fig. 3, 6, 8) comprising a tubular member (1) having a lumen and a distal end (14, 6); a distal portion (9) having a proximal end (for example 15) detachably connected (as in joined) to the tubular member (for example as seen in Fig. 6, the expansion of the strips 16, against the inner surface of the tubular member will connect or join the distal tip to the tubular member), the proximal end having an annular groove (18, Fig. 8) that receives the distal end of the tubular member (when the strips 16 are expanded against the tubular member as in Fig. 6) , wherein when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts to have a smaller diameter than the tubular member (Fig. 3). The distal end (19) of the distal portion has a smaller diameter than a diameter of the tubular member, when secured to the distal end of the tubular member (Figs. 3 and 6). A tubular insertion device (10) is inserted through the lumen of the tubular member. The tubular insertion device is configured to detach the distal portion from the tubular member when inserted through the tubular member (The distal portion is detached from the tubular member when the insertion device is inserted into the tubular member up until the point the insertion device reaches member (18), for example Fig. 3). A recovery device (7) for withdrawing the distal portion through the tubular member when the distal portion has been detached from the tubular member.

Dormia further discloses a method of using the device that includes detachably securing a proximal end of a distal portion to the distal end of the tubular member (as seen in Fig. 6, the expansion of the strips 16, against the inner surface of the tubular member will secure the distal tip to the tubular member) by receiving the distal end of the tubular member (6) in an annular groove (18, Fig. 8) at the proximal end of the distal portion, inserting the distal end into an orifice (Col 4, line 43), selectively detaching the distal portion [(Col 4, line 57-60) and alternatively (Fig. 3)], the distal portion contracting to have a diameter smaller than the tubular member (compare Figs. 3 and 6) and withdrawing the distal portion through the tubular member (Col 4, Lines 57-60). The step of selective detaching (in other words, selecting to detach or selecting to not detach the distal tip) includes inserting a tubular insertion device (10) for contacting the inner wall of the distal portion (18) (Fig. 1) (selecting to detach or not is determined by how far the insertion device is inserted through the tubular member). The distal tip is conical and tapered.

6. Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dotolo (US 5,931,776).

7. Dotolo discloses an orifice introducer device comprising: a tubular member (10) having a distal end; a distal portion (12) having a proximal end configured to be detachably connected to the tubular member (Col 2, Line 20-22), the proximal end having an annular groove (16) that receives the distal end of the tubular member (see Fig. 2), the distal portion being selectively detachable when the orifice introducer device

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is positioned in the orifice, wherein, when detached from the distal end of the tubular member, the proximal end of the distal portion contracts so as to have a smaller diameter than the tubular member (as tip 12 dissolves it will contract to have a smaller diameter). When secured to the distal end of the tubular member, a distal end of the distal portion has a smaller diameter than the tubular member.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 20 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127) in view of Puskas (US 6,042,538).

10. Dormia discloses all the limitations of the invention substantially as claimed as stated above except for the surgical stapler. Dormia does disclose the insertion of electrically operated surgical appliances such as electrically driven scalpels.

11. Puskas discloses inserting instruments into an endoscope that include retractors, staplers, suction devices, and electric devices.

12. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a surgical stapler into the invention of Dormia in the place of an electrical scalpel since the two surgical devices were art recognized equivalents at

the time of the invention was made. Additionally, it is well known in the art to use endoscopes as a guiding in device for surgical staplers.

13. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127).

14. Dormia discloses the invention substantially as claimed as stated above. However Dormia fails to disclose that the recovery device is a string. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to replace the tubular recovery device with a string because it would reduce the overall profile of the device. Applicant has not disclosed that the string provides an advantage, is used for a particular purpose or solves a stated problem. In fact, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the introducer. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

15. Applicant's arguments filed 04/04/08 have been fully considered but they are not persuasive. Regarding the Dormia reference, applicant argues that the mandrel head (distal portion) is not connected to the distal end of the jacket (tubular member). However, "connected" merely requires that the two elements be *united, joined, or linked*. When the distal portion is expanded as in Fig. 6 and the spring segments (16) are

forced against the tubular member, the two elements are in fact joined or united. The “annular groove”, merely requires a *narrow cut or indentation*. As clarified above, the indentation at (18) is best seen in Fig. 8. When the distal portion is expanded as in Fig. 6, the groove (18) would receive the end (6) of the tubular member. Regarding the method step of detaching, applicant argues that Dormia fails to disclose "detaching by inserting a tubular insertion device through the tubular member. However, the claim requires the step of "selective detaching", which was interpreted as selecting to detach or not detach. The choice of selecting to detach or not detach includes inserting the insertion device into the tubular member and is determined by how far the insertion device is inserted.

16. Regarding the Dotolo reference, applicant argues that dissolvable can not be considered detachably connected. However, initially the distal portion is connected (fig. 2) then it dissolves resulting in the distal portion no longer being connected, thus the distal portion is detached. Regarding the limitation “contract”, it merely requires *becoming smaller; shrinking*, where dissolving would be equivalent to shrinking or becoming smaller. Regarding the limitation “annular groove”, it merely requires a *narrow cut or indentation*, where the shoulder is equivalent to an indentation.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731